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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,272	10/17/2001	Michael Rud Lassen	LASSEN=2A	4444

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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/978,272

Applicant(s)
Lassen et al

Examiner
Mosher

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/24/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8-28, 30-43, and 45-58 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-28, 30-43, and 45-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

The after-final amendment filed April 24, 2003 has been entered. Finality is withdrawn, and new grounds of rejection are presented.

Claim Rejections - 35 USC § 112

Claims 1-3, 8-28, 30-43, and 45-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the first occurrence of "RS virus related biological cell" has been changed to "RS virus infected cell or and RS virus biological particle", which clarifies the meaning. However, "RS virus related biological cell" still is found in claim 1, parts ii and iii, and the claim ends with a comma after "solid support" in part v. This affects the dependent claims.

In claim 42, part (a), should "said kit comprising" be deleted? In step (d), "diagnosing said infectious condition" does not relate to the steps preceding it; should the claim say something like "wherein detecting the presence of the RS virus infected cell or RS virus biological particle indicates an infectious condition" ? If claim 42, step (d) is amended, claim 43 may need to be amended for consistency.

In claim 56, is the claim intended to depend from claim 52, or is it really intended to depend from claim 55?

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Claim Rejections - 35 USC § 103

Claims 1-3, 8-20, 24, 25, 28, 30-36, 42, 45, 46, and 48-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swiekosz et al (Journal of Clinical Microbiology 27:1151-1154, 1989) in view of Tsutsumi et al (Journal of Clinical Microbiology 37:2007-2009, 1999), Ouchi et al (J. Infect. Chemother. 5:230-222, 1999), and Lihme et al (US 5,543,332). This is a modification of the previous rejection, in response to applicant's arguments. Applicant convincingly argued that the polymer-conjugated detection material of Osikowitz was not the conjugate comprising a polymeric carrier bound to a targeting species and a labeling species, as required by the claims. Therefore the rejections based in part on the teachings of Osikowitz have been withdrawn, and replaced with similar rejections based on the teachings of Lihme. As discussed in the previous Office action, Swiekosz teaches an immunoassay kit for direct detection of RSV, and Tsutsumi and Ouchi teach an immunochromatography kit for direct detection of another respiratory virus, with advantages of speed, convenience, and sensitivity. These publications do not teach a polymeric conjugate, as required by the claims. However, Lihme teaches that a known method of enhancing the sensitivity of an immunoassay is to attach an antibody and a plurality of markers to a polymeric carrier, see column 5, lines 18-28. Lihme teaches further advantages of attaching a plurality of antibodies to the carrier, see column 9, line 56 through column 10, line 23. Lihme also teaches a wide variety of suitable polymers, see column 11, line 54 through column 12, line 12, and a wide variety of suitable markers, see column 13, lines 30-65. It would have been within the ordinary skill of the art to further modify the assay

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of Swiekosz by using the polymeric carrier of Lihme, to further improve the sensitivity of the assay, with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 21-23, 26, 27, 37-41, 43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swiekosz et al (Journal of Clinical Microbiology 27:1151-1154, 1989) in view of Tsutsumi et al (Journal of Clinical Microbiology 37:2007-2009, 1999), Ouchi et al (J. Infect. Chemother. 5:230-222, 1999), and Lihme et al (US 5,543,332) as applied to claims 1-3, 8-20, 24, 25, 28, 30-36, 42, 45, 46, 48-58 above, and further in view of Sheeran et al (Pediatric Infectious Disease Journal 18:115-122, 1999, abstract only cited). These claims differ from the above in further requiring detection of an inflammatory indicator, specifically one or more cytokines. Sheeran teaches that certain cytokines are correlated with disease severity in RSV infection. Therefore one of ordinary skill would have been motivated to include means to detect these cytokines in an RSV diagnostic kit and method, for the purpose of indicating disease severity. Therefore the invention as a whole is prima facie obvious, absent unexpected results. Applicant argues that Sheeran gives no information about the performance of the test and especially not information about the polymeric carrier; however, the other cited references teach performance of an assay, and Lihme particularly teaches the polymeric carrier for improving performance.

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Shigetou et al (EP 0957364) and Khaw et al (WO 98/38513) are cited as of interest, as disclosing other antibody-polymer-marker conjugates used to increase the sensitivity of immunoassays.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone numbers for this Group are now (703) 872-9306 for Before Final responses, and (703) 872-9307 for After Final responses. Faxes for this Group can also be sent to (708) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 7, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600